

REMARKS

The Claim Amendments

Applicants have amended claim 1 to improve its form and to recite “[a]n isolated nucleic acid molecule comprising a regulatory element operably linked to a part of a nucleic acid sequence in antisense orientation thereto” Support for this amendment may be found, for example, on page 8, lines 18-20 and on page 10, lines 26-29. Applicants also have amended claim 1 to improve its form and to delete section (c). Applicants have amended claims 22 and 34 to improve their form.

None of these amendments adds new matter. Their entry is requested. After entry of the amendments, claims 1, 16, 22-26, 28 and 34-35 will be pending.

The Rejection under 35 U.S.C. § 101

The Examiner has rejected claims 16, 22-24 and 28 under 35 U.S.C. § 101 as directed to non-statutory subject matter. Specifically, the Examiner contends that claims 16 and 22-24 are drawn to plant cells comprising a native maize gene encoding debranching enzyme and that claim 28 is drawn to plant propagation material that does not necessarily comprise the transgene. The Examiner indicates that amending claim 16 to recite a host cell transformed with the nucleic acid molecule of claim 1 or comprising a vector comprising said nucleic acid molecule would obviate this rejection. Applicants traverse in view of the claims, as amended.

Applicants disagree with the Examiner. The nucleic acid molecule recited in claim 1 is an isolated nucleic acid molecule. Claim 16 and the claims depending from it recite that the host cells and plant propagation material comprise this isolated nucleic acid

molecule. The isolated nucleic acid molecule of claim 1 may be introduced into the cells or propagation material recited in claims 16, 22-24 and 28 by any method known to one of skill in the art, e.g., by Agrobacterium-mediated transformation, biolistic delivery, electroporation, protoplast fusion, or microinjection (see, e.g., page 24, lines 27 to 31). It is not necessary that the claims recite that the cells or plants are “transformed” with the nucleic acid molecule of claim 1. Thus, contrary to the Examiner’s assertion, these claims do not read on naturally occurring cells and plants that comprise the nucleic acid molecule.

However, applicants’ amendment of claim 1 to recite “[a]n isolated nucleic acid molecule comprising a regulatory element operably linked to a part of a nucleic acid sequence in antisense orientation thereto . . .” obviates this rejection.

The Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1, 16, 22-26, 28 and 34-35 under 35 U.S.C. § 112, second paragraph, as indefinite.

Specifically, the Examiner contends that it is unclear whether the recitation “when introduced in antisense orientation” indicates that the nucleic acid molecule actually is in antisense orientation with respect to a promoter or whether this is merely an intended use, thus rendering “antisense orientation” meaningless. The Examiner also contends that claims 22 and 34 are indefinite in their recitation of “has a sequence identity of more than 95%” because it is unclear against which sequence the identity is calculated. The Examiner suggests amendments to claims 1, 22 and 34 that would obviate these rejections.

Applicants have amended claims 1, 22 and 34 along the lines suggested by the Examiner, thus obviating the rejections.

The Rejection under 35 U.S.C. § 112, First Paragraph

Written Description

The Examiner has rejected claims 1, 16, 24-26 and 28 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention at the time the application was filed. The Examiner states that the claims are broadly drawn to isolated nucleic acid molecules or parts thereof which hybridize under conditions of unspecified stringency to the exemplified sequences, and host cells containing them. The Examiner contends that the specification only demonstrates the obtention or characterization of the native maize debranching enzyme gene and its use. The Examiner states that the specification does not provide guidance for the identification of non-exemplified sequences which would hybridize to the exemplified gene under conditions of low or moderate stringency. The Examiner cites *University of California v. Eli Lilly and Co.*, 43 USPQ 2d 1398 (Fed. Cir. 1997) for the proposition that a written description of an invention must enable one of skill in the art to distinguish it from other materials and to visualize or recognize the identity of the members of the claimed genus. Applicants traverse in light of the claims as amended.

As described above, applicants have deleted part (c) of claim 1, which recited a nucleic acid sequence hybridizing to the nucleic acid sequence of (a) or (b). Thus, amended claim 1, and the claims depending from it, are not drawn to isolated nucleic acid

molecules or parts thereof which hybridize under conditions of unspecified stringency to the exemplified sequences. The nucleic acid molecules of the amended claims are structurally defined as having a defined sequence similarity to a defined nucleic acid sequence. Further, the nucleic acid molecules are functionally defined because they are able to exert an antisense effect on the expression of a debranching enzyme. Thus, the claimed nucleic acid molecules are adequately described by the specification as filed.

Enablement

The Examiner also has rejected claims 1, 16, 24-26 and 28 under 35 U.S.C. § 112, first paragraph, for lack of enablement.

The Examiner acknowledges that the specification is enabling for claims directed to an isolated nucleic acid molecule comprising a plant promoter operably linked to a part of a nucleic acid sequence, which nucleic acid sequence is at least 90% identical to SEQ ID NO: 1 or to a sequence encoding SEQ ID NO: 2, wherein said part is sufficient to inhibit debranching enzyme activity when introduced in antisense orientation. However, the Examiner contends that the specification does not reasonably provide enablement for claims broadly drawn to isolated nucleic acid molecules which hybridize thereto under conditions of low or moderate stringency.

Applicants traverse in light of the claims, as amended.

As discussed above, applicants have deleted part (c) of claim 1. Thus, the claims recite a nucleic acid sequence that has more than 90% sequence identity to SEQ ID NO: 1 or to a sequence encoding SEQ ID NO: 2, wherein said part is sufficient to inhibit

debranching enzyme activity when introduced in antisense orientation, which the Examiner acknowledges are enabled. The Examiner has acknowledged the enablement of such amended claims.

The Rejection under 35 U.S.C. § 102(b)

The Examiner has rejected claims 16, 22-24 and 28 under 35 U.S.C. § 102(b) as anticipated by Black et al., “Genetic Interactions Affecting Maize Phytoglycogen and the Phytoglycogen-Forming Branching Enzymes,” Genetics 53: 661-68 (1966) (“Black”) and Doehlert et al., “Two Classes of Starch Debranching Enzymes from Developing Maize Kernels,” J. Plant Physiol. 138: 566-572 (1991) (“Doehlert”) and has rejected claims 16, 22-26 and 28 as anticipated by Gordon-Kamm et al., “Transformation of Maize Cells and Regeneration of Fertile Transgenic Plants,” Plant Cell 2:603-18 (1990) (“Gordon-Kamm”).

Specifically, the Examiner contends that claims 16, 22-24 and 28 are broadly drawn to maize cells and propagation materials which inherently contain the native maize debranching enzyme gene and states that Black, Doehlert and Gordon-Kamm teach such maize cells and propagation materials. The Examiner also contends that claims 25-26 are drawn to transgenic maize plants with an unspecified transgene, which plants also contain the native debranching enzyme genes. The Examiner states that Gordon-Kamm teaches transformed maize plants and progeny which would inherently contain the native maize debranching enzyme gene. The Examiner states that the proposed amendments to claim 16 to overcome the rejection under 35 U.S.C. § 101 would obviate this rejection.

Applicants traverse in light of the claims, as amended.

As discussed above, claim 16 and the claims depending from it recite that the host cells and plant propagation material comprise an isolated nucleic acid molecule, specifically the isolated nucleic acid molecule of claim 1. Applicants have amended claim 1 to recite “[a]n isolated nucleic acid molecule comprising a regulatory element operably linked to a part of a nucleic acid sequence in antisense orientation thereto” Therefore, the description in Black, Doehlert and Gordon-Kamm of plant cells and propagation materials comprising an unisolated, native maize debranching enzyme is inapposite. None of these references describes a cell or plant propagation material comprising the isolated nucleic acid molecule of amended claim 1. Thus, none of Black, Doehlert and Gordon-Kamm anticipate applicants’ claimed invention.

The Examiner has rejected claims 1 and 16 under 35 U.S.C. 102(b) as anticipated by WO 95/09922 (“Miller Brewing”) and James et al., “Characterization of the Maize Gene Sugary1, a Determinant of Starch Composition in Kernels,” Plant Cell 7:417-29 (1995) (“James”). Specifically, the Examiner states that claims 1 and 16 are broadly drawn to host cells which contain a part of an isolated nucleic acid molecule which hybridizes to a maize debranching enzyme under conditions of unspecified stringency. The Examiner contends that Miller Brewing teaches an isolated pullulanase gene and that James teaches an isolated debranching enzyme gene from maize. The Examiner contends that the genes in Miller Brewing and James would inherently hybridize under conditions of low stringency to the claimed maize debranching enzyme. The Examiner indicates that deletion of section (c) of claim 1 would obviate these rejections.

Applicants have amended claim 1 to delete section (c), thus obviating the rejection.

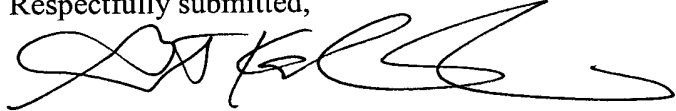
Finally, the Examiner has rejected claims 1, 16, 24-26 and 28 under 35 U.S.C. § 102(b) as anticipated by WO 96/03515 (“Monsanto”). Specifically, the Examiner contends that Monsanto teaches maize plant cells and plants transformed with an isolated isoamylase gene that would inherently hybridize under conditions of low stringency to the maize debranching enzyme gene. The Examiner also contends that the gene would inherently reduce debranching enzyme gene expression if it were introduced into the plant cell in antisense orientation. The Examiner indicates that deletion of part (c) of claim 1 and the proposed amendments to claim 1 to obviate the rejection under 35 U.S.C. § 112, first paragraph, would obviate this rejection as well.

Applicants have amended claim 1 to delete section (c) and to recite “[a]n isolated nucleic acid molecule comprising a regulatory element operably linked to a part of a nucleic acid sequence in antisense orientation thereto,” thus obviating the rejection.

Conclusion

For the reasons presented above, applicants request that the Examiner allow claims 1, 16, 22-26, 28 and 34-35 to issue.

Respectfully submitted,



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Copy of claims 1, 22 and 34 marked up pursuant to 37 C.F.R. § 1.121(c)(1)(ii)

1. (Three Times Amended) An isolated nucleic acid molecule comprising a regulatory element operably linked to a part of a nucleic acid sequence in antisense orientation thereto, wherein the nucleic acid sequence is selected from the group consisting of:

(a) a nucleic acid sequence encoding a protein comprising the amino acid sequence of SEQ ID NO: 2;

(b) a nucleic acid sequence that is SEQ ID NO: 1[;

(c) a nucleic acid sequence hybridizing to the nucleic acid sequence of (a) or (b)]; and

([d]c) a nucleic acid sequence that has more than 90% sequence identity to (a) or (b);

wherein the [part] nucleic acid molecule is sufficient to reduce the expression of a debranching enzyme in a plant cell [when introduced in antisense orientation].

22. (Twice Amended) The host cell according to claim 16, wherein said nucleic acid sequence [of (d)] has a sequence identity of more than 95% to (a) or (b).

34. (Amended) The nucleic acid molecule of claim 1, wherein said nucleic acid sequence [of (d)] has a sequence identity of more than 95% to (a) or (b).